EXHIBIT 27

FEDERAL REGISTER

Vol. 80 Tuesday,
No. 178 September 15, 2015

Part II

Department of Justice

Drug Enforcement Administration
Masters Pharmaceuticals, Inc.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–39]

Masters Pharmaceuticals, Inc.; Decision and Order

On August 9, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Masters Pharmaceuticals, Inc. (hereinafter, Respondent). ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration Number RD0277409, pursuant to which it is authorized to distribute controlled substances in schedules II through V, at the registered location of 11930 Kemper Springs, Cincinnati, Ohio, and the denial of any pending application to renew or modify its registration, on the ground that its "continued registration is inconsistent with the public interest." *Id.* (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order specifically alleged that on April 21, 2009, Respondent entered into a Memorandum of Agreement (MOA) with DEA, pursuant to which it agreed "to 'maintain a compliance program to detect and prevent [the] diversion of controlled substances as required under the [Controlled Substances Act] and applicable DEA regulations.'" *Id.* (quoting MOA at ¶ II.1.a). The Order also alleged that in the MOA, Respondent "'acknowledg[ed] and agree[d] that the obligations undertaken . . . do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.'" *Id.*

The Order then alleged that notwithstanding "the MOA, the specific guidance provided to [Respondent] by DEA, and the public information readily available regarding the oxycodone epidemic in Florida, and in the United States, [Respondent] failed to maintain effective controls against the diversion of controlled substances . . . in violation of 21 U.S.C. 823(b)(1) and (e)(1)." *Id.* at 1–2. The Order then alleged that from April 1, 2009 through December 31, 2009, Respondent distributed more than 37 million dosage units of oxycodone nationally and that nearly 25 million dosage units "were distributed to its Florida customers," and that the latter distributions "well exceeded" its distributions to customers in other States.[1] *Id.* at 2. The Order further alleged that during 2010, Respondent distributed 37.86 million dosage units of oxycodone nationally, of which nearly 24.4 million dosage units "were distributed to its Florida customers."[2] *Id.* Finally, the Order alleged that between January 1 and March 31, 2011, Respondent distributed 6.1 million dosage units of oxycodone nationally, of which approximately 2.76 million dosage units "were distributed to its Florida customers."[3] *Id.*

Next, the Show Cause Order alleged that "[s]ince at least 2009, the majority of [Respondent's] largest purchasers of oxycodone . . . have been retail pharmacies in the State of Florida who [it] knew or should have known were distributing controlled substances based on . . . prescriptions that were issued for other than a legitimate medical purpose and outside [of] the usual course of professional practice." *Id.* at 3. The Order then made allegations regarding Respondent's distributions of oxycodone 30 mg to eight pharmacies. More specifically, the Order alleged that:

1. "From April 1, 2009 through November 30, 2010, [it] distributed approximately 591,800 dosage units . . . to Tru-Valu Drugs";
2. "From April 1, 2009 through January 31, 2011, [it] distributed approximately 993,100 dosage units . . . to The Drug Shoppe";
3. "From April 1, 2009 through March 31, 2011, [it] distributed approximately 333,000 dosage units . . . to the Medical Plaza Pharmacy";
4. "From April 1, 2009 through September 30, 2010, [it] distributed approximately 1.275 million dosage units . . . to Englewood Specialty Pharmacy";
5. "From April 1, 2009 through December 31, 2010, [it] distributed approximately 570,700 dosage units . . . to City View Pharmacy";
6. "From January 1, 2009 through November 30, 2010, [it] distributed approximately 1.7 million dosage units . . . to Lam's Pharmacy";
7. "From April 1, 2009 through August 31, 2009, [it] distributed approximately 637,400 dosage units . . . to Morrison's RX"; and
8. "From January 1, 2009 through December 2009, [it] distributed approximately 351,600 dosage units . . . to Temple Terrace Pharmacy."

Id.

The Show Cause Order then alleged that Respondent "consistently ignored and/or failed to implement its own due diligence and suspicious order monitoring policies, compromising the effectiveness of those policies." *Id.* Continuing, the Order alleged that "notwithstanding the large quantities of controlled substances ordered by [its] retail pharmacy customers, [Respondent] failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted" and "ignor[ed] and/or fail[ed] to document red flags of diversion present at many of its retail pharmacy customers." *Id.* Finally, the Order alleged that Respondent "failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 CFR 1301.74(b)." *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. ALJ Ex. 3. The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to ALJ Gail Randall (hereinafter, ALJ). ALJ's Recommended Decision (R.D.), at 1. Following pre-hearing procedures, *see generally* ALJ Exs. 5–11, the ALJ conducted an evidentiary hearing on February 24 through 28 and March 3 through 4, 2014, in Arlington, Virginia. Following the hearing, both parties filed briefs containing their proposed findings of fact and conclusions of law.

On June 19, 2014, the ALJ issued her Recommended Decision. Applying the public interest standard of 21 U.S.C. 823(b), the ALJ noted that the relevant factors were factors one—the maintenance of effective controls against diversion—and four—Respondent's experience in the distribution of controlled substances.

The ALJ rejected the Government's contention that Respondent had failed to report numerous suspicious orders, which it filled and shipped, upon subsequently determining that the customer was likely engaged in diverting controlled substances. R.D. at 154–61. Noting that the relevant regulation requires the reporting of a suspicious order "when discovered," 21 CFR 1301.74(b), the ALJ opined that neither the regulation's language nor its purpose "supports the conclusion that a registrant is required to review past orders from pharmacies the registrant later learns may be diverting controlled

[1] By contrast, the Order alleged that during this period, Respondent distributed approximately 1.47 million dosage units of oxycodone to its Nevada customers, 1.27 million to its Tennessee customers, 1.14 million to its Pennsylvania customers, and 1.09 million to its New Jersey customers. ALJ Ex. 1, at 2.

[2] By contrast, the Order alleged that during 2010, Respondent distributed approximately 2.8 million dosage units of oxycodone to its Nevada customers, 2.14 million to its Tennessee customers, 1.7 million to its New Jersey customers, and 1.37 million to its Pennsylvania customers. ALJ Ex. 1, at 2.

[3] By contrast, the Order alleged that during this period, Respondent distributed approximately 600,000 dosage units of oxycodone to its Tennessee customers, 415,000 to its New Jersey customers, 304,000 to its Pennsylvania customers, and 192,000 to its Nevada customers. ALJ Ex. 1, at 2.

substances." *Id.* at 157. The ALJ did, however, conclude that the regulation "impose[s] a duty to report past orders [that] the registrant *actually* discovers were suspicious." *Id.* at 158. However, based on her review of the record, the ALJ concluded that Respondent had only failed to report a single suspicious order. *Id.*

Turning to the Government's contention that Respondent had failed to maintain effective controls against diversion, the ALJ concluded that the Government's evidence as to the volume of Respondent's sales to Florida and the eight pharmacies in particular did not support a finding that it was in violation of this duty. *Id.* at 164–67. As the ALJ explained, "the sheer volume of a respondent's controlled substances sales or purchases, without some kind of contextual background to link the sales to the respondent's duty under the CSA, cannot be used to indicate that the distributor's registration would be against the public interest." *Id.* at 164. The ALJ further noted that the Government did not present a "statistical expert or any other evidence to explain why the volume of Respondent's sales was necessarily indicative of diversion." *Id.* at 166. She also credited the testimony of Respondent's statistical expert that the "shipments to the DEA-identified pharmacies rarely stand out from the rest of the monthly shipments"; that because Respondent does not have access to the Agency's ARCOS database, "it cannot compare its shipments to [those] made by other distributors"; that "Respondent's business model as a secondary supplier made comparisons across pharmacies practically useless"; and that comparing its distributions to Florida customers with those in other States was not "very meaningful because there [are] so many factors that are relevant." *Id.* at 167 (citations omitted).

Next, the ALJ rejected the Government's contention that Respondent failed to follow its own policies and procedures. *Id.* at 170–79. The ALJ first found that Respondent's Policies and Procedures required that an order placed on compliance hold by its Suspicious Order Monitoring System (SOMS) be subject to additional due diligence which included: (1) Contacting the customer to discern the reason for the deviation in size, pattern, or frequency; (2) independently verifying the reason stated by the customer; and (3) conducting a complete file review. *Id.* at 73–74, 76–77. While the Government cited numerous instances in which Respondent's employees released orders without documenting having performed the above steps, the ALJ rejected its contention, reasoning that Respondent's Policies and Procedures did "not require documentation of the reasons for the release of a held order." *Id.* at 171. And while noting "that Respondent documented some reasons for abnormal orders," she further reasoned that "[t]he mere absence of documentation—documentation that is not required by Respondent's Policies and Procedures, DEA regulations, or any established industry standard—does not constitute substantial evidence that the undocumented act did not occur." *Id.* at 172; *see also id.* at 173–74, 176.

Next, the ALJ addressed the Government's contention that Respondent failed to properly use the Utilization Reports (URs) which it obtained from its pharmacy customers. *Id.* at 179–95. While the ALJ found that Respondent was required under its policies and procedures to obtain a UR from a pharmacy customer whenever it placed an order on compliance hold and yet repeatedly failed to do so, *id.* at 181, she otherwise rejected the Government's contention that Respondent did not properly utilize the URs in its review of the held orders. *Id.* at 181–92.

In rejecting the Government's contention, the ALJ explained that because DEA was obligated under a Memorandum of Agreement (MOA) to conduct a compliance review and notify Respondent of any deficiencies in its policies and procedures and failed to do so with respect to its use of the URs, the MOA bars the Agency "from sanctioning Respondent for not implementing additional UR analyses into its Policies and Procedures." R.D. at 186. While noting the parties' agreement "that controlled substance ratios are an important aspect that should be investigated prior to shipping controlled substances," the ALJ then reasoned that "[t]he Government offered no evidence that accurate information regarding controlled substance ratios can *only* be acquired through URs." *Id.* at 188–89. She also rejected the Government's contention that Respondent's actions in editing or deleting orders that were placed on hold by the SOMS established that it did not maintain effective controls against diversion or failed to report suspicious orders, noting that Respondent edited and deleted orders "for business reasons." *Id.* at 196.

While acknowledging that the Government had proved that Respondent had failed to report a single suspicious order, the ALJ reasoned that "Respondent fills many orders each year and has reported hundreds of suspicious orders, so one minor oversight does not render the entire system ineffective." *Id.* at 201. The ALJ thus concluded that Respondent had "substantially complied with 21 CFR 1301.74(b)," and that its failure to report the suspicious order did not justify the revocation of its registration. *Id.*

As for her finding that Respondent had violated its own policies and procedures by failing to obtain a UR every time an order was held by the SOMS, the ALJ reasoned that "the relevant question . . . is not simply whether Respondent failed to follow its policies, but whether such failure rendered [its] system [for maintaining effective controls] ineffective . . . and/or constituted negative experience distributing controlled substances so as to justify revocation." *Id.* The ALJ then explained that Respondent's failure to follow its policies and procedures did not render them ineffective *per se* and that the Government was required to show that diversion was the "direct and foreseeable consequence" of its failure to follow its policy in order to establish that its due diligence program was ineffective. *Id.* at 202. Because "the Government made no showing that the shipments Respondent made without requiring URs were likely to be diverted," or "that updated URs, had they been requested, would have indicated that the drugs were likely to be diverted," the ALJ concluded that Respondent's failure to obtain the URs did not "justify revocation." *Id.* The ALJ thus recommended that Respondent be allowed to retain its registration and that the Administrator approve any pending renewal application. *Id.* at 203.

Both parties filed Exceptions to the ALJ's Recommended Decision. Thereafter, the record was forwarded to me for final agency action. Having reviewed the record in its entirety, and having carefully considered the ALJ's Recommended Decision as well as the parties' Exceptions,[*] I respectfully reject the ALJ's decision for reasons explained throughout this decision.

To summarize my reasons, I do agree with the ALJ that the Government's evidence as to the volume of Respondent's sales to the Florida pharmacies and the State in general does not constitute substantial evidence that the pharmacies were likely diverting controlled substances. I also agree with the ALJ's rejection of the Government's contention that Respondent, upon terminating a customer because it was likely diverting controlled substances, was obligated to review the customer's past orders and

[*] I address the various exceptions raised by the Parties throughout this decision.